REMARKS

The Office Action mailed October 29, 2010 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-44 are pending in this application. Claims 27-43 are withdrawn from further consideration as being drawn to a non-elected species. Claims 1, 16, and 25 are amended herein to correct minor informalities. Applicants submit that no new matter is introduced.

Claim Objections

Claims 16 and 25 stand objected to because of minor informalities. Claim 16 recites a "tubular means" which the Examiner prefers to be recited as "guidewire tubular means." Claim 16 is amended accordingly, without conceding the propriety of the objection. Claim 1 is also amended accordingly so that all instances of "tubular means" are preceded by "guidewire" in the claims. Claim 25 refers to the "tubular portion," which the Examiner requests be changed to "the proximal tube portion." Claim 25 is so amended herein. Accordingly, in view of the above, Applicants respectfully request withdrawal of the claim objections.

Claim Rejections – 35 U.S.C. § 103

Claims 1-9, 11, 12, 15-20, 24-26, and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 2003/0109886 to Keegan et al. ("Keegan"). Claims 21-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Keegan in view of US 2008/026506 to Griffen et al. ("Griffen"). Claim 10 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Keegan in view of USPN 6,945,989 to Betelia et al. ("Betelia"). Claims 13-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Keegan in view of USPN 5,603,698 to Roberts et al. ("Roberts"). Applicants respectfully traverse these rejections.

Regarding sole independent claim 1, the Examiner alleges that Keegan shows in FIG. 19(a) a combination of sheath 4 and junction piece 9, which is alleged as equivalent to the claimed sleeve. The Examiner admits that "Keegan fails to configure the guidewire tubular means (101) and the

primary shaft to overlap in length," but alleges that such an arrangement is illustrated in Figure 18, that Keegan states the guide tube 101 can be extended rearward, that such a modification would "require a mere change in size or location of a component," and that therefore, it would have been obvious to one of ordinary skill in the art." (Office Action, p. 3.) Applicants respectfully submit that Keegan does not render the pending claims obvious for at least the following reasons.

First, it is noted that nowhere in the Office Action is there an allegation that Keegan discloses "a proximal end of the sleeve form-fitted over the primary shaft" as recited in independent claim 1. It is clear that Keegan does not show or describe such a feature. As noted by the Examiner, the required radially inwardly tapering portion proximal of the proximal end opening of the guidewire tubular means is shown only by Keegan if one combines the sheath 4 and junction piece 9. This is because the sheath itself does not include a proximal inwardly tapering portion. However, even assuming, *arguendo*, that the combination of these components is equivalent to the claimed sleeve (a proposition with which the Applicants disagree, have argued against previously, and discuss in more detail below), the required limitation that the sleeve be "form-fitted over the primary shaft" is still not shown by Keegan. This is due to the fact that the connection piece 9, being a separate and distinct component with two openings, one for the catheter body 2 and the other for the guidewire 10, which is disclosed as "profiled to form a smooth transition from the profile of the sheath 4 to the profile of the catheter body 2" (Keegan, paragraph [0139]) does not allow for a low "form-fitted" profile. The distinction between the claimed form-fitted sleeve and the Keegan combination of sheath and junction piece cannot be glossed over as a mere obvious variation. The form-fitted sleeve provides clear advantages, an important one of which is that it avoids/prevents issues with withdrawal of the delivery device through a guiding catheter following deployment. Specifically, the Keegan system, formed by a combination of components with edges, rather than a single form-fitted sleeve, can catch on the shoulder of the guiding catheter upon withdrawal, leading to complications with the procedure in general, and with decoupling of the Keegan combined components in particular.

Second, as alluded to above, Applicants disagree that the claimed form-fitted sleeve with a radially inwardly tapering portion is equivalent to the Keegan combination of connection piece 9 and sheath 4, as alleged by the Examiner. Importantly, as Keegan states, "[b]oth the catheter body 2 and the sheath 4 are attached to the junction piece 9 by bonding using an adhesive." (Keegan, paragraph [0130].) It is axiomatic that one integral component is preferable to two or more adhered components in an intravascular device. This is due to the inherent risk of an intraluminal detachment of one component from the other, which is an ever-present safety consideration in the area of trans-luminal surgical devices. For example, in a PTCA application described in paragraph [0003] of Keegan, the connection of the junction piece 9 to the sheath 4 and the catheter body 2 is a mere 10 cm away from the heart. Applicants claimed invention of a form-fitted sleeve does not carry the inherent risk found in the Keegan device, and therefore the claimed invention distinguishes over Keegan at least on this basis. Furthermore, use of the junction piece 9 by Keegan presents additional risks not present in the claimed form-fitted sleeve. For example, as one skilled in the art of catheter manufacture is well-aware, regardless of how smoothly one intends to transition one piece to another, the connection points between components present sharp edges that are not preferable in a trans-luminal application due to potential adverse reactions by the body. Further, such unfavorable sharp edges are not limited to the connection points between the junction piece 9 and the catheter body 2 and sheath 4, but are also presented by the junction piece 9 itself at least at the openings thereof. (*See* Keegan FIGS. 19(a), (c), and (d).)

Third, Applicants disagree that the asserted modification of extending the guide tube 101 of FIG. 19(a) proximally in order to meet the claimed limitation of a "guidewire lumen having a length that longitudinally overlaps a length of the primary shaft" is obvious as alleged. The Examiner alleges that because the Keegan FIG. 18 device shows an overlap, therefore it would be obvious to extend the guide tube 101 of FIG. 19(a). However, Applicants submit that the design differences in the two examples lead one skilled in the art away from such a modification. In particular, extending proximally guide tube 101 of FIG. 19(a) would cause the catheter profile to <u>increase</u> at the proximal end in order for the junction piece 9 to accommodate the guide tube 101. Such a profile increase is unfavorable to one skilled in the art, and therefore one would not be lead to make the proposed

modification. The Examiner also alleges that such a modification is taught by Keegan from the statement that the guide tube 101 can be extended rearward. However, Applicants respectfully submit that the Keegan statement, "the guide tube 101 may alternatively or additionally extend proximally externally of the sheath 4" does not suggest to one skilled in the art that the guide tube 101 and catheter tube 2 overlap in length for at least the aforementioned reason related to increased profile (i.e., a rearward extension of the guide tube 101 would be accompanied by a respective lengthwise reduction of the catheter tube 2 in a proximal direction so that the connection piece diameter does not need to increase to accommodate the overlap).

Accordingly, in view of the above, Applicants submit that independent claim 1 is patentable over Keegan. Claims 2-9, 11, 12, 15-20, 24-26, and 44 are patentable because they depend from patentable independent claim 1, and also because they recite features not shown or described by Keegan. Thus, Applicants respectfully request favorable reconsideration and withdrawal of the rejection of claims 1-9, 11, 12, 15-20, 24-26, and 44 under 35 U.S.C. § 103.

With respect to dependent claims 10, 13-14, and 21-23, without conceding the propriety of the asserted combinations, or the allegations in the Office Action, Applicants submit that each depends from patentable independent claim 1, in view of the above, and is therefore patentable. Thus, Applicants respectfully request favorable reconsideration and withdrawal of these rejections under 35 U.S.C. § 103.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicant of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Submitted herewith is the fee for a one-month extension of time. If further fees are due, please charge our Deposit Account No. 50-2191, under Order No. 101671.0057P from which the undersigned is authorized to draw.

Dated: February 28, 2011

Respectfully submitted,

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